

REMARKS

The present application has been considered in view of the Office Action that was mailed on January 26, 2010. Claims 10-35 are currently pending. By the present Amendment, Applicants have amended the written description, as well as claims 10, 25, 26, and 29, canceled claim 13, and added new claim 35 for consideration. Applicants respectfully submit that these amendments do not introduce any new matter, and are fully supported by the specification. In view of the following remarks and arguments, Applicants respectfully submit that each of pending claims 10-35 is allowable over the references of record, and accordingly, respectfully request reconsideration and allowance of these claims.

In the Office Action, the drawings were objected to under 37 C.F.R. 1.83(a) for failure to show each and every feature of the claimed subject matter. Specifically, it was argued that the drawings fail to show "at least two tissue engaging members," or "at least two "jaw members," since the drawings fail to illustrate the inclusion of more than two "tissue engaging member" or more than two "jaw members."

By the present Amendment, Applicants have amended the claims to remove the recitation of "at least two tissue engaging member" and "at least two jaw members." (Emphases added).

Applicants respectfully submit that the drawings illustrate every feature of the subject matter recited in the pending claims, and as such, that the drawings comply fully with the requirements of 37 C.F.R. 1.83(a). Accordingly, Applicants respectfully submit that the objection to the drawings has been overcome, and respectfully request withdrawal of the objection to the drawings.

Additionally, the specification was objected to for failing to include the patent numbers of the parent cases.

By the present Amendment, Applicants have amended the pertinent section of the written description to include the patent numbers of the issued parent cases.

Accordingly, Applicants respectfully request withdrawal of the objection to the specification.

Claims 10-24 and 29-34 were rejected under 35 U.S.C. §112, first paragraph, for failure to comply with the enablement requirement. It was asserted that the claims contain subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, it was argued that:

[t]he specification does not enable for more than two engaging members and more than two jaw members in such a way as to enable one skilled in the art to which it pertains of how the invention is made or used with more than two engaging members and more than two jaw members within the body. (Office Action, page 4).

Additionally, claims 10-24 and 29-34 were rejected under 35 U.S.C. §112, first paragraph, for failure to comply with the written description requirement. It was asserted that the claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the present application was filed, has possession of the claimed subject matter. Specifically, it was argued that “[a]t the time the application was filed, the inventors failed to disclose more than two tissue engaging

members and more than two jaw members,” and therefore, that “the limitations ‘at least two tissue engaging members’ and ‘at least two jaw members’ are considered new matter.” (Office Action, page 4).

As mentioned above, Applicants have amended the claims herein to remove the recitation of “at least two tissue engaging member” and “at least two jaw members.” (Emphases added).

Accordingly, Applicants respectfully submit that the claims comply fully with the enablement and written description requirements set forth in 35 U.S.C. §112, first paragraph, and that the rejection of claims 10-24 and 29-34 under 35 U.S.C. §112, first paragraph, has been overcome. As such, Applicants respectfully request withdrawal of the rejection of claims 10-24 and 29-34 under 35 U.S.C. §112, first paragraph.

Claims 10-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,165,183 to Kuehn, *et al.* (hereinafter “Kuehn”) in view of U.S. Patent No. 5,403,326 to Harrison, *et al.* (hereinafter “Harrison”). Applicants respectfully submit, however, that the combination of Kuehn and Harrison fails to render the subject matter of claims 10-34 obvious, as presented herein.

As a condition for patentability, 35 U.S.C. §103(a) indicates that “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art,” then the subject matter is not patentable. (Emphasis added).

As amended, independent claim 10 recites “[a]n apparatus for substantially closing a vascular opening in a vessel” that includes, “a housing,” “tissue engaging members” that are

"longitudinally and reciprocally movable relative to the housing between a retracted position and an advanced position," "jaw members connected to the housing and positioned adjacent the tissue engaging members and being movable independently thereof," and "a deployment member." According to amended independent claim 10, the "deployment member" is:

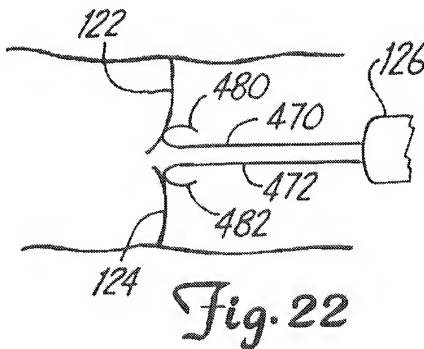
connected to the tissue engaging members such that the tissue engaging members are longitudinally movable relative to the housing and between the jaw members, the tissue engaging members being movable in a distal direction to facilitate engagement with the vascular tissue adjacent the vascular opening to orient the vascular tissue in a predetermined orientation, and thereafter, being movable in a proximal direction to draw the vascular tissue between the jaw members to facilitate seizure by the jaw members.

As amended, independent claim 25 recites "[a]n apparatus for substantially closing a vascular opening in a vessel" that includes "a housing," "an elongated shaft at least partially positioned within the housing, the elongated shaft defining a longitudinal axis and including a proximal end, a distal end, and a lumen extending between the proximal and distal ends, the lumen being configured and dimensioned to receive a prepositioned guidewire" such that "the apparatus is movable along the guidewire," tissue engaging members at least partially extending from the housing," and "jaw members connected to the housing and disposed adjacent the tissue engaging members."

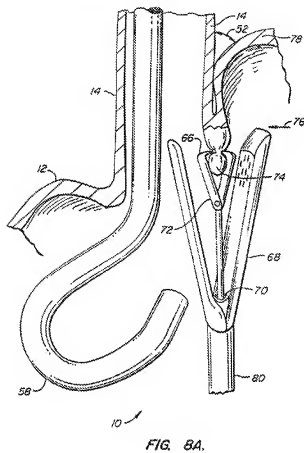
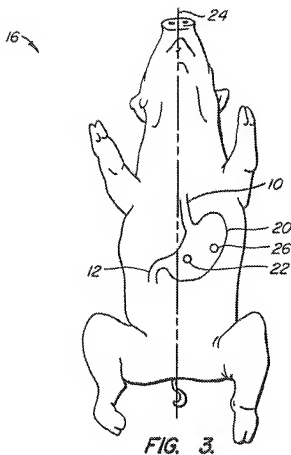
As amended, independent claim 29 recites "[a]n apparatus for substantially closing a vascular opening in a vessel" that includes "a housing," "an elongated shaft at least partially positioned within the housing, the elongated shaft defining a longitudinal axis and including a proximal end, a distal end, and a lumen extending between the proximal and distal ends," wherein the claimed "lumen" is "configured and dimensioned to receive a prepositioned guidewire such that the apparatus is movable along the guidewire," and the "elongated shaft"

further includes recesses formed adjacent the distal end.” Amended independent claim 29 further recites that the “apparatus” includes “tissue engaging members disposed adjacent the distal end of the housing,” and “jaw members connected to the housing and positioned adjacent the tissue engaging members.” According to amended independent claim 29, the “jaw members” include “attachment members depending inwardly therefrom towards the longitudinal axis” that are “configured and dimensioned to adjoin the tissue adjacent the vascular opening, that attachment members being further configured and dimensioned for receipt by the recesses formed adjacent the distal end of the elongated shaft.”

Kuehn relates to “the repair of mitral and tricuspid valves exhibiting valve regurgitation,” and more particularly, “to apparatus and methods suitable for a less invasive repair of a mitral or tricuspid heart valve.” (Col. 1, lines 5-8). In one embodiment of the disclosure, Kuehn describes a cardiac catheter 126 through which hooks 470, 472 are deployed for grasping leaflets 122, 124 of the mitral valve. (See col. 10, lines 4-14; FIG. 22 below).



Harrison relates to a method of fundoplication of a patient's stomach to the esophagus. (See col. 2, lines 43-44). In one embodiment of the disclosure, Harrison describes the placement of a flexible pediatric gastroscope 18 into the lumen 32 of a patient's stomach 20, which is angled anteriorly to transilluminate a site for a medial endoscopic port 22. (See col. 5, lines 12-15; FIG. 3 below). Subsequently, a tissue grasper, e.g., a stapler 68 including moveable jaws 66, is introduced through the port 22, and is positioned to grasp tissue at the gastroesophageal junction (GEJ). (See col. 6, line 61 – col. 7, line 1; FIG. 8A below).



In the Office Action, the hooks 470, 472 of Kuchen's cardiac catheter 126 were characterized as the claimed "tissue engaging members." It was acknowledged that Kuchen fails to disclose the claimed "jaw members," but the jaws 66 of Harrison's tissue grasper were relied

upon for disclosure of this concept. (See Office Action, pages 5-6). Specifically, it was argued that it would have been obvious "to provide Kuehn's apparatus with at least two jaw members as taught by Harrison." (Office Action, page 6).

While Kuehn indicates that the disclosed device may include a gripper element 402 and a fastener applicator element 404, the gripper 402 and the fastener applicator 404 are disclosed as being "adjacent each other, as shown in FIG. 17," (col. 8, lines 61-62) (emphasis added), or arranged for relative movement "by sliding in a tube, track, or similar mechanisms." (Col. 8, line 64; FIG. 17 below).

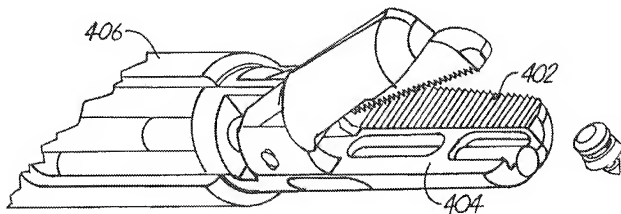


Fig. 17

As seen above in FIG. 17, the gripper 402 and the fastener applicator 404 are thus positioned in side-by-side relation. Kuehn fails to provide any indication, either in the written description or in the figures, that the gripper 402, or the hooks 470, 472 (FIG. 22 above), which, to reiterate, were characterized as the claimed "tissue engaging members" in the Office Action, may be positioned "between the jaw members," as recited in amended independent claim 10. (Emphasis added).

Additionally, Kuehn states that "with fastener applicator 404 in a distal withdrawn position, gripper 402 can grab leaflets 122, 124," and thereafter, that the "fastener applicator 404 can be opened in the withdrawn position and slid forward to apply a tack on captured leaflet edges." (Col. 8, line 66 – col. 9, line 3). In other words, the fastener applicator 404 is moved distally to engage the captured tissue.

In contrast, amended independent claim 10 recites that the "tissue engaging members" are "movable in a proximal direction to draw the vascular tissue between the jaw members." (Emphasis added).

Moreover, Applicants respectfully submit that neither Kuehn, nor Harrison, discloses, or even suggests, any structure that can be analogized to the "elongated shaft" recited in amended independent claims 25 and 29, which includes "a lumen . . . configured and dimensioned to receive a prepositioned guidewire such that the apparatus is movable along the guidewire."

Furthermore, neither Kuehn, nor Harrison, discloses, or even suggests, an "elongated shaft" that includes "recesses formed adjacent the distal end" such that "attachment members" included on the "jaw member" are positionable within the "recesses," as substantially recited in amended independent claim 29.

For at least these reasons, *inter alia*, even if it is assumed, *arguendo*, that the characterizations of Kuehn and Harrison proffered in the Office Action are accurate, and that Kuehn and Harrison are properly combinable under the MPEP, Applicants respectfully submit that the combination of Kuehn and Harrison fails to suggest the subject matter of amended independent claims 10, 25, and 29 as a whole. Therefore, Applicants respectfully submit that the combination of Kuehn and Harrison fails to render the subject matter of amended independent

claims 10, 25, and 29 obvious, and as such, that amended independent claims 10, 25, and 29 are allowable over Kuehn in view of Harrison under 35 U.S.C. §103(a). Since claims 11-24, 26-28, and 30-34 depend either directly or indirectly from one of amended independent claims 10, 25, and 29, and include each element recited therein, for at least the reasons that amended independent claims 10, 25, and 29 are allowable over Kuehn in view of Harrison under 35 U.S.C. §103(a), *inter alia*, Applicants respectfully submit that claims 11-24, 26-28, and 30-34 are also allowable over Kuehn in view of Harrison under 35 U.S.C. §103(a).

Claims 10-34 were also rejected on the ground of non-statutory obviousness-type double patenting over claims 1-9 of U.S. Patent No. 6,248,124 (hereinafter "the '124 patent"), and claims 1-25 of U.S. Patent No. 6,676,685 (hereinafter "the '685 patent").

In the interests of advancing prosecution, Applicants will execute a terminal disclaimer with respect to claims 1-9 of the '124 patent, and claims 1-25 of the '685 patent, upon the indication that claims 10-34 are otherwise allowable.

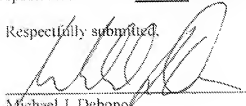
As mentioned above, Applicants have added new claim 35 for consideration herein. Applicants respectfully submit that new claim 35 recites a unique combination of features that is neither taught, nor suggested, by the references of record. For example, since new claim 35 depends indirectly from amended independent claim 10, which Applicants respectfully submit is allowable in accordance with the discussion above, and includes each element recited therein, for at least the reasons that amended independent claim 10 is allowable, *inter alia*, Applicants respectfully submit that new claim 35 is also allowable.

In view of the foregoing remarks and arguments, Applicants respectfully submit that claims 10-35 are allowable over the references of record, and accordingly, respectfully request allowance of these claims.

Should the Examiner believe that a telephone interview may facilitate prosecution of this application, or resolve any outstanding matters, the Examiner is sincerely invited to contact Applicants' undersigned representative at the number indicated below.

Please charge any deficiency, as well as any other fee(s) which may become due under 37 C.F.R. §1.16 and/or 1.17 at any time during the pendency of this application, or credit any overpayment of such fee(s), to Deposit Account No. 21-0550. Also, in the event any extensions of time for responding are required for the pending application(s), please treat this paper as a petition to extend the time as required, and charge Deposit Account No. 21-0550 therefor.

Respectfully submitted,



Michael J. Debono
Reg. No. 62,877
Attorney for Applicants

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road, Suite 420
Melville, New York 11747
Telephone: (631) 501-5700
Facsimile: (631) 501-3526

Correspondence Address:

Chief Patent Counsel
Teco Healthcare Group LP
d/b/a Covidien
15 Hampshire Street
Mansfield, MA 02048